

Notice of Allowability

Application No.

10/809,757

Examiner

Juliet C. Switzer

Applicant(s)

YATES ET AL.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed 8/18/05 and interview 8/25/05 and declarations filed 9/13/05.
2. ☒ The allowed claim(s) is/are 4, 17, 24 and 25.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 0805.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

820

Art Unit: 1634

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Benjamin Adler on 8/25/05.

The application has been amended as follows:

In **claim 4**, the language after "comprising:" has been deleted and the following language has been therefor:

"a primer pair consisting of the primer sequences SEQ ID NO: 1 and SEQ ID NO: 3; and a primer pair consisting of the primer sequences SEQ ID NO: 2 and SEQ ID NO: 3."

In **claim 17**, the language after "C3435T" has been deleted and following language has been inserted therefor:

"consisting of the primer sequences SEQ ID NO: 1 and SEQ ID NO: 3 or consisting of the primer sequences SEQ ID NO: 2 and SEQ ID NO: 3."

The following claims have been added:

24. A method of genotyping human multidrug resistance gene (MDR1) single nucleotide polymorphism C3435T, comprising the steps of:

preparing DNA samples from an individual;

Art Unit: 1634

amplifying said DNA with a first primer pair comprising a wild type-specific primer and common reverse primer, wherein the first primer pair is a primer pair consisting of the primer sequences SEQ ID NO: 1 and SEQ ID NO: 3 and also amplifying said DNA with a second primer pair comprising a mutant-specific primer and common reverse primer, wherein the second primer pair is a primer pair consisting of the primer sequences SEQ ID NO: 2 and SEQ ID NO: 3 and

identifying the products of said DNA amplification,

wherein the presence of products amplified by said mutant-specific primer and said reverse primer indicate said individual has at least one "T" allele at position 3435 of the MDR1 gene.

Claim 25. The method of claim 24, wherein said products of DNA amplification are identified by a method selected from the group consisting of real-time fluorescence-based analysis, melt curve analysis and gel electrophoresis.

Withdrawal of Restriction Requirement

2. Claims 4 and 17 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 24 and 25, directed to the process of making or using the patentable product, drawn to an invention previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Process claims 24 and 25 hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Reasons for Allowance

3. The following is an examiner's statement of reasons for allowance: The prior art does not teach or suggest primer pairs comprising a primer that consists of instant SEQ ID NO: 3. While the prior art of record provides a general motivation to select reverse primers for allele specific amplification downstream of the location of a polymorphic site, the prior art does not provide specific teaching regarding the selection of a primer consisting of SEQ ID NO: 3 in particular, see in particular applicant's remarks regarding SEQ ID NO: 3 on page 9 of the response filed. Newly added claims 24 and 25 are allowable at least because they utilize a primer which consists of instant SEQ ID NO: 3.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday through Wednesday, from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached by calling (571) 272-0745.

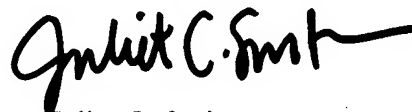
The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is

Art Unit: 1634

(571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Juliet C. Switzer
Primary Examiner
Art Unit 1634

September 15, 2005